

REMARKS

Claims 20-38 are currently pending in the application. By the amendment, claims 20-23, 26 and 30-33 have been amended merely for formal matters and claims 39 and 40 have been added for the Examiner's consideration. No new matter has been entered.

Accordingly, reconsideration and withdrawal of the pending rejections are requested in view of the instant amendments and the accompanying remarks.

Amendment Fully Supported by the Original Disclosure

The above amendments do not add new matter to the application and are fully supported by the specification. For example, support for added claims 39 and 40, which recite, "when the actuator/locking fin is advanced to extend the surgical blade, the single use indicator is one of irreversibly collapsed and inverted by contact with the ribbed interior wall surfaces", is provided at page 7, lines 5-9 of the specification.

Further, claims 21-23, 26 and 31-33 have been amended to correct antecedent issues.

Further, independent claim 20 was amended to provide proper antecedent basis for the "ribbed interior wall surfaces, blade carrier and surgical blade" and "molded plastic" was deleted. Further still, independent claim 30 was amended to provide proper antecedent basis for the "ribbed interior wall surfaces, blade carrier and surgical blade" and "molded plastic" was deleted.

Acknowledgement of Cited Items

Applicant notes with appreciation the Examiner's consideration of the documents

cited in the Information Disclosure Statement filed in the present application on February 2, 2004 by the return of the initialed and signed copy of the PTO-1449 Form accompanying the Information Disclosure Statement.

Drawings

As neither the Examiner nor the Patent Office Draftsperson has objected to the originally submitted drawings, Applicant understands that these drawings are acceptable.

Obviousness-type Double Patenting Rejection is Moot

Applicant traverses the Examiner's assertions that claims 20-21, 24-26, 30-31 and 35 are unpatentable over claims 1-2, 5-6 and 9-10 of US Patent No. 6,645,216 under the judicially created doctrine of obviousness-type double patenting.

However, in order to expedite the prosecution of the instant application towards allowance, Applicant has submitted, concurrently herewith, an executed Terminal Disclaimer to render the above-noted rejection moot.

By the submission of this Terminal Disclaimer, neither Applicant nor Assignee is making any representation or admission regarding the propriety of the Examiner's judicially created obviousness type double patenting rejection or of the propriety of any other double patenting rejection in the absence of the submission of this Terminal Disclaimer. As noted above, Applicant is not acquiescing to the Examiner's arguments and in order to solely advance the Applicants' business

interests, a terminal disclaimer in compliance with 37 CFR 1.321(c) is being filed along with this response to overcome this rejection.

35 U.S.C. §102 Rejections

1. Over COHN

Claims 20-23, 27-28, 30-33 and 36 are rejected under 35 U.S.C. § 102(b) as being anticipated by Cohn *et al.* (US Patent No. 6,053,929) (hereafter "COHN"). Applicant respectfully traverses this rejection for at least the following reasons.

Applicant submits that in contrast to the requirement of 35 U.S.C. § 102(b), COHN does not disclose every element of the claimed invention. In this case, Applicants' independent claim 20, as currently amended, recites, *inter alia*:

- " iii) *a single-use indicator window; and*
- iv) *a retaining element for engaging a distal end of a leaf spring; and*
- b) *wherein the blade carrier comprises:*
 - i) *a first end adapted for engaging the surgical blade;*
 - ii) *a second end comprising a leaf spring to assist in surgical blade retraction, the leaf spring having a proximal and a distal end; and*
 - iii) *a central portion comprising the actuator/locking fin and a single-use indicator.*".

Applicants' independent claim 30, as currently amended, recites, *inter alia*:

- " iii) *a single-use indicator window; and*
- b) *wherein the blade carrier comprises:*
 - i) *a first end adapted for engaging the surgical blade;*
 - ii) *a second end comprising a leaf spring to assist in surgical*

blade retraction, the leaf spring having a proximal and a distal end, the distal end of the leaf spring being joined to the housing by a live hinge; and

- iii) a central portion comprising the actuator/locking fin and a *single-use indicator*.”.

While the Examiner asserts COHN discloses all the features of independent claims 20 and 30, Applicant submits that a review of COHN fails to support this assertion. In fact, nothing in COHN discloses or suggests a *single-use indicator window*, nor a *single-use indicator*, as recited in independent claims 20 and 30, as currently amended.

Applicant notes that, COHN shows a scalpel 410 having a groove 436 that extends from the blade holder 420 from a distal terminus 438 onto a handle 412 to terminus 440 on one side of the scalpel. See Col. 9, lines 56-67. However, in contrast to the instant invention, Applicant notes that COHN shows a shield 430 having a cantilever 432 with a digital activation section 434, such that bosses 442 engage grooves 436 when the shield 430 is positioned in either the proximal or distal positions (see Figures 25-29 and Col. 10 lines 1-20), but COHN does not show the recited *single-use indicator window*, as at least recited in independent claims 20 and 30. Moreover, Applicant finds no disclosure of the recited *single-use indicator*, as at least recited in independent claims 20 and 30. In fact, COHN teaches away from the instant invention showing that when shield 430 reaches a terminus position (either 438, 440), bosses 442 serve to provide a practitioner perceptible “snap” (as the bosses engage in the enlargement and allow cantilever 432 to return to a rest position), so as to assist the practitioner in recognition of the completion of the desired movement of the shield (see

Col. 10, lines 13-200), as well as having a shield positioned to cover the blade to prevent accidental cuts (i.e., when the surgeon looks away from the patient being operated on to pick-up the surgical blade) (see Col. 10, lines 6-8), not as a *single-use indicator* as at least claimed in Applicant's claimed invention.

Moreover, the Examiner states that COHN teaches a *single-use indicator window* (page 3 last full paragraph of the instant Office Action), and refers to Figures 25, 28-29, character reference element 432 to support this assertion. However, contrary to the Examiner's assertions, character reference element 432 is disclosed in COHN as a cantilever (see Col. 9, line 55 to Col. 10, line 19), not as a *single-use indicator window* (or single use indicator of any manner).

Thus, COHN fails to provide any disclosure of the above-noted features at least recited in the independent claims, as currently amended.

Because COHN fails to disclose each and every recited feature of at least independent claims 20 and 30, Applicant submits that the Examiner has failed to provide an adequate evidentiary basis to support an anticipation rejection under 35 USC § 102(b). Therefore, the 102(b) rejection of independent claims 20 and 30 should be withdrawn. Further, Applicant submit that claims 21-23, 27-28, 31-33 and 36 are allowable at least for the reason that these claims depend from allowable base claims and because these claims recite additional features that further define the present invention.

Accordingly, Applicant requests that the Examiner reconsider and withdraw the rejection of the claims 20-23, 27-28, 30-33 and 36 under 35 U.S.C. § 102 (b) and indicate that these claims are allowable.

2. Over GRINGER

Claims 20-22, 24-26, 29-30, 34-35 and 38 are rejected under 35 U.S.C. § 102(b) as being anticipated by Gringer (US Patent No. 6,058,607) (hereafter "GRINGER"). Applicant respectfully traverses this rejection for at least the following reasons.

Applicant submits that in contrast to the requirement of 35 U.S.C. § 102(b), GRINGER does not disclose every element of the claimed invention. In this case, Applicants' independent claim 20, as currently amended, recites, *inter alia*:

"A single-use surgical scalpel, comprising:

- a) a molded plastic housing having an upper and a lower radiused edge, and ribbed interior wall surfaces, the ribbed interior wall surfaces of the molded plastic housing defining a channel for slidable engagement of a blade carrier, the channel comprising:
 - i) one open end through which a surgical blade is extended during use;
 - ii) a slot through the lower radiused edge for slidable engagement of an actuator/locking fin, the slot being adapted for retaining a blade carrier in a surgical blade-extended position;
 - iii) a single-use indicator window; and
 - iv) a retaining element for engaging a distal end of a leaf spring; and
- b) wherein the blade carrier comprises:
 - i) a first end adapted for engaging the surgical blade;
 - ii) a second end comprising a leaf spring to assist in surgical blade retraction, the leaf spring having a proximal and a distal end; and
 - iii) a central portion comprising the actuator/locking fin and a single-use indicator.".

Applicants' independent claim 30, as currently amended, recites, *inter alia*:

"A single-use surgical scalpel, comprising:

- a) a molded plastic housing having an upper and a lower radiused edge, and ribbed interior walls surfaces, the ribbed interior wall surfaces of the molded plastic housing defining a channel for slidable engagement of a blade carrier, the channel comprising:
 - i) one open end through which a surgical blade is extended during use;
 - ii) a slot through the lower radiused edge for slidable engagement of an actuator/locking fin, the slot being adapted for retaining a blade carrier in a blade-extended position; and
 - iii) a single-use indicator window; and
- b) a molded plastic blade carrier comprising:
 - i) a first end adapted for engaging the surgical blade;
 - ii) a second end comprising a leaf spring to assist in blade retraction, the leaf spring having a proximal and a distal end, the distal end of the leaf spring being joined to the housing by a live hinge; and
 - iii) a central portion comprising the actuator/locking fin and a single-use indicator.".

While the Examiner asserts GRINGER discloses all the features of independent claims 20 and 30, Applicant submits that a review of GRINGER fails to support this assertion. In fact, nothing in GRINGER discloses or suggests a *single-use indicator window*, nor a *single-use indicator*, as recited in independent claims 20 and 30, as previously presented.

Applicant notes that GRINGER shows the thumb piece 10 integral with the blade carrier 24 and extending through slot 8 so that movement of the thumb piece 8 along the slot by the user causes projection and retraction of the cutting blade 12 (see Figures 7 and 8 and Col. 6, lines 26-52), but GRINGER does not show the recited a *single-use indicator*, nor a *single-use indicator window*, as at least recited in

independent claims 20 and 30.

However, contrary to the Examiner's assertions, character reference element 10 is disclosed in GRINGER as a thumb piece (see, column 6, lines 26, 34-35 and 63; column 7, lines 9, 14 and 66 and column 8, lines 9, and 14), not as a *single-use indicator* (or *single-use indicator* of any manner). Moreover, Applicant respectfully submits that nothing in the GRINGER reference indicates a *single-use indicator*. The Examiner refers to Figures 4, 7-8 and element (10) of GRINGER to support this assertion (that GRINGER teaches a *single-use indicator*), however, the Examiner makes no argument as to how a thumb piece could function as a *single-use indicator*. Furthermore, Gringer makes no claim that their device is a *single use indicator*, or for that matter a *single-use indicator* of any means.

Thus, GRINGER fails to provide any disclosure of the above-noted features at least recited in the independent claims, as currently amended.

Because GRINGER fails to disclose each and every recited feature of at least independent claims 20 and 30, Applicant submits that the Examiner has failed to provide an adequate evidentiary basis to support an anticipation rejection under 35 USC § 102(b). Therefore, the 102(b) rejection of independent claims 20 and 30 should be withdrawn. Further, Applicant submit that claims 21-22, 24-26, 29, 34-35 and 38 are allowable at least for the reason that these claims depend from allowable base claims and because these claims recite additional features that further define the present invention.

Accordingly, Applicant requests that the Examiner reconsider and withdraw the rejection of the claims 20-22, 24-26, 29-30, 34-35 and 38 under 35 U.S.C. § 102 (b)

and indicate that these claims are allowable.

CONCLUSION

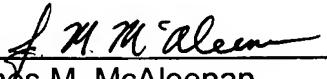
In view of the foregoing, it is submitted that none of the references of record, either taken alone or in any proper combination thereof, anticipate or render obvious Applicant's invention, as recited in each of claims 20-38 and new claims 39-40 which depend from an allowable base claim. The applied references of record have been discussed and distinguished, while significant claimed features of the present invention have been pointed out.

Further, any amendments to the claims which have been made in this response and which have not been specifically noted to overcome a rejection based upon the prior art, should be considered to have been made for a purpose unrelated to patentability, and no estoppel should be deemed to attach thereto.

Summary

Accordingly, reconsideration of the outstanding Office Action and allowance of the present application and all the claims therein are respectfully requested and now believed to be appropriate. Any deficiency or overpayment should be charged or credited to Deposit Account No. 500282.

Respectfully submitted,
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